



News Release

PO Box 360, Trenton, N.J. 08625-0360

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Commissioner

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Department of Health and Senior Services Proposes to Readopt with Amendments N.J.A.C. 8:21, the Rules Governing Food and Drugs

The Consumer and Environmental Health Services of the Public Health Protection and Emergency Preparedness Branch of the Department of Health and Senior Services is proposing to readopt N.J.A.C. 8:21, which establishes requirements to protect consumers from adulterated and misbranded foods, drugs, cosmetics and medical devices.

The Department is proposing amendments throughout N.J.A.C. 8:21-3A, which addresses the registration of wholesale distributors of prescription drugs, to strengthen those provisions as they relate to combating the threat to consumer safety posed by counterfeit drugs. The proposed amendments would respond to the recommendation of the Food and Drug Administration in its February 2004 report, "Combating Counterfeit Drugs," that states adopt and enforce strong, proven anti-counterfeiting regulations based on the model rules for licensure of wholesale drug distributors developed by the National Association of Boards of Pharmacy (NABP). Consequently, the Department is proposing amendments to N.J.A.C. 8:21-3A that would incorporate many of the requirements contained in the NABP model rules for licensure of wholesale drug distributors.

In addition, consistent with the NABP model rules, the Department is proposing amendments to extend the scope of its authority under N.J.A.C. 8:21-3A from regulating the wholesale distribution of prescription drugs to regulating the wholesale distribution of all drugs. The proposed amendments would further the Department's objective of combating the proliferation of counterfeit drugs in New Jersey.

N.J.A.C. 8:21-7 addresses Frozen Desserts. The Department is proposing no changes to this subchapter. N.J.S.A. 24:10-73.1 requires the Department to convene a public hearing in connection with rulemaking addressing frozen desserts. Therefore, the Department will convene a public hearing limited to the subject of the proposed readoption without change of N.J.A.C. 8:21-7, Frozen Desserts, on Tuesday, November 15, 2005 from 10:00 a.m. to 12:00 noon in Conference Room B, University Office Plaza, 3635 Quakerbridge Road, Hamilton Township, NJ 08019-1247. As this is a secured building, persons planning to attend the public hearing or wishing to be placed on the list of speakers are requested to telephone Ms Steinouer at (609) 588-7483 by no later than November 9, 2005, so that convenient access to the public hearing can be prearranged.

The proposal appears in the October 17, 2005 issue of the New Jersey Register. The public has until December 16, 2005 to comment on the proposal. Persons wishing to comment on the proposal must submit their comments in writing to James A. Brownlee, M.P.H., Director, Consumer and Environmental Health Services, P O Box 369, Trenton, NJ 08625-0369. Written comments must be postmarked on or before December 16, 2005, which is the close of the 60-day public comment period.

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